



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

7590 03/22/2002
Leanne C Price Esq
FibroGen Inc
225 Gateway Blvd
South San Francisco, CA 94080

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,239

Applicant(s)

CHANG ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 22-29 and 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-15,21,30 and 42-74 is/are rejected.
- 7) ☒ Claim(s) 4,8,16-20 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6,8</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-dated alterations have been made to the address of Inventor, James W. Polarek. See 37 CFR 1.52(c).

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-21, 30 and 42-74, as well as SEQ ID NO:18 and SEQ ID NO:29 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the search can be made without burden to include Group V and the amino acid sequences containing SEQ ID NO:18 and SEQ ID NO:29. This is not found persuasive because applicant's response has not demonstrated that there is no burden on the additional search. Restriction is proper when two or more claimed inventions are either independent or distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups would have required a search of additional art areas. For example, in Group V, it would require additional searches for post-translation enzymes such as prolyl hydroxylase and the conditions such as melting temperature for hydroxylation. Regarding including other amino acid sequences, it would also require additional sequence searches. Therefore, coexamination of each of these inventions would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate

Art Unit: 1653

the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claim 12 is objected to because the term "homogeneous" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7, 10, 11, 14, 21, 30, 63, 69 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 7 and 69 are indefinite because of the use of the term "partially hydroxylated". The term "partially hydroxylated" renders the claim indefinite, it is unclear to what extent the recombinant gelatin is hydroxylated as to "partially hydroxylated" and which amino acid residues are hydroxylated.

Art Unit: 1653

6. Claim 10 is indefinite because of the use of the term “fully hydrolyzed”. The term “fully hydrolyzed” renders the claim indefinite, it is unclear what products are obtained after fully hydrolysis, and whether the fully hydrolyzed gelatin has the properties of gelatin.

7. Claim 11 is indefinite because of the use of the term “partially hydrolyzed”. The term “partially hydrolyzed” renders the claim indefinite, it is unclear to what extent the recombinant gelatin is hydrolyzed as to “partially hydrolyzed”.

8. Claim 14 is indefinite because of the use of the term “is derived from”. The term “is derived from” renders the claim indefinite, it is unclear how different the recombinant gelatin obtained from one type of collagen is as compared to the parent compound as to “is derived from”. Use of the term “is obtained from” is suggested.

9. Claims 21 and 30 are indefinite because the claim contains non-elected sequences.

10. Claim 63 is indefinite because of the use of the terms “device” and “a subject”. The terms “device” and “a subject” render the claim indefinite, it is unclear what the device and the subject are.

11. Claim 70 is indefinite because of the use of the term “fully-hydroxylated”. The term “fully-hydroxylated” renders the claim indefinite, it is unclear to what extent the recombinant gelatin is fully hydroxylated and which amino acid residues are hydroxylated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1653

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note that the gelatin indicated in the reference is not distinguishable from the recombinant gelatin of the claimed invention.

12. Claims 1, 44, 64, 65, 67 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Pilliero *et al.* (U. S. Patent 5,330,773).

Pilliero *et al.* disclose a method of making a cheese food product containing gelatin solution (column 1, lines 55-68; claims 1, 64, 65 and 67), wherein the gelatin is used as a stabilizing agent (column 2, lines 22-26; claim 44) and a coating agent (column 2, lines 26-42; claim 68).

13. Claims 1, 64 and 66 are rejected under 35 U.S.C. 102(b) as anticipated by Grossman *et al.* (U. S. Patent 5,194,282).

Grossman *et al.* disclose a food product where a part or all of the fat content is replaced by gelatin (column 2, lines 55-61; claims 1, 64 and 66).

14. Claims 1, 43, 54, 55 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Russell *et al.* (U. S. Patent 5,827,852).

Russell *et al.* disclose gelatin is used for coating a pharmaceutical composition, and the gelatin shells including the hard gel capsules (claim 54) and soft gel capsules (claim 55) are prepared (column 4, lines 50-60; claims 1, 43 and 68).

15. Claims 1, 42, 45, 64 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Mason *et al.* (U. S. Patent 5,565,227).

Mason *et al.* disclose a dry coating composition (column 1, lines 65-67; claims 1, 64 and 68) for imparting the texture, taste and appearance of batter fried foods containing gelatin as a

Art Unit: 1653

binding agent (column 2, line 4; claim 42) and for film coating (column 1, lines 45-46; column 2, lines 34-43; claim 45).

16. Claims 1, 5, 6, 45, 46, 49, 64 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by Todd (U. S. Patent 4,356,202).

Todd discloses a composition in pliable sheet form using a gelatin matrix is prepared for wrapping a foodstuff (column 2, lines 3-45; claims 1, 45, 64 and 68), wherein the gelatin, a gelling agent (column 3, line 55; claims 46 and 49) has a bloom strength in excess of 50 (column 3, lines claims 5 and 6).

17. Claims 1 and 51 are rejected under 35 U.S.C. 102(b) as anticipated by Bolinger (U. S. Patent 3,578,492).

Bolinger discloses twistless yarns contain a sizing composition comprising an adhesive agent such as gelatin (column 2, lines 43-45; claims 1 and 51).

18. Claims 1, 47, 48, 49 and 71 are rejected under 35 U.S.C. 102(b) as anticipated by Zviak *et al.* (U. S. Patent 3,840,338).

Zviak *et al.* disclose a cosmetic composition (claims 1 and 71) may contain thickening agents such as gelling agents, which includes emulsifying agents, e.g., gelatin (column 6, lines 22-41; claims 47, 48 and 49).

19. Claims 1, 45, 50 and 72 are rejected under 35 U.S.C. 102(b) as anticipated by Helmstetter (U. S. Patent 4,055,554).

Helmstetter discloses a gelatin composition (claim 1) contains chemically modified dialdehyde polysaccharides as gel strength enhancer, wherein the gelatin is the protective colloid

Art Unit: 1653

(claim 50), and the composition can be used for industrial coating (column 3, lines 55-column 4, line 17; claims 45 and 72).

20. Claims 1 and 73 are rejected under 35 U.S.C. 102(b) as anticipated by McAleer *et al.* (U. S. Patent 4,147,772).

McAleer *et al.* disclose a stabilized lyophilized or liquid viral vaccine contains a partially hydrolyzed gelatin and a cell culture medium (column 1, lines 64-68; claims 1 and 73).

21. Claims 1, 52, 57 and 74 are rejected under 35 U.S.C. 102(b) as anticipated by Beyer *et al.* (Br. J. Anesthesia 78, 44-50 (1997)).

Beyer *et al.* disclose 3% a modified fluid gelatin and 6% hydroxyethyl starch are used for volume replacement in major orthopedic surgery (pages 45-48; claims 1, 52, 57 and 74).

22. Claims 1, 52, 61 and 62 are rejected under 35 U.S.C. 102(b) as anticipated by Di Silvio *et al.* (J. Mater. Sci.: Mater. Med. 5, 819-823 (1994)).

Di Silvio *et al.* disclose gelatin is used as a vehicle for drug delivery in two different delivery systems: microsphere (claims 1, 52 and 62) and as a coating on titanium implants (pages 819-820; claim 61).

23. Claims 1 and 56 are rejected under 35 U.S.C. 102(b) as anticipated by Kanatani *et al.* (Agri. Biol. Chem. 53, 1185-1187 (1989)).

Kanatani *et al.* disclose the protoplasts of *L. plantarum* are formed with the addition of gelatin as a plasma expander (pages 45-48; claims 1 and 56).

24. Claims 1-3, 9, 11 and 13-15 are rejected under 35 U.S.C. 102(a) as anticipated by Werten *et al.* (Yeast 15, 1087-1096 (August, 1999)).

Art Unit: 1653

Werten *et al.* disclose recombinant non-hydroxylated gelatins (claims 1 and 9) based on mouse type I or rat type III collagen sequences are secreted from methylotrophic yeast *Pichia pastoris*, which has very high level of heterologous protein secreted (claim 13; page 1090-1093). The recombinant gelatins, COL1A1-1 and COL1A1-2 have molecular weights of 11-27 and 11-53 kDa, respectively (Table 1; claims 2, 3, 14 and 15), and COL3A1 is hydrolyzed by a protease in the fermentation medium (page 1091, left column; claim 11).

25. Claims 1, 59 and 60 are rejected under 35 U.S.C. 102(a) as anticipated by Luks *et al.* (Am. J. Obstet. Gynecol. 181, 995-996 (October, 1999)).

Luks *et al.* disclose gelatin sponge plugs are introduced in the primate model (pages 995-996, claims 1, 59 and 60).

26. Claims 1, 52 and 58 are rejected under 35 U.S.C. 102(a) as anticipated by Mligiliche *et al.* (East African Med. J. 400-406 (July, 1999)).

Mligiliche *et al.* disclose a biodegradable gelatin conduits are introduced in the mice model (pages 401-404, claims 1, 52 and 58).

27. Claims 4, 8, 16-20 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

28. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

Art Unit: 1653

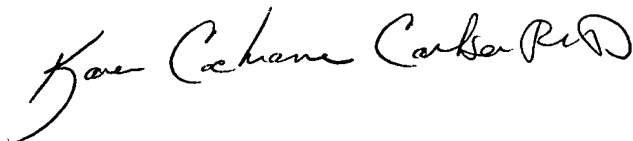
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

March 19, 2002



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER